

## **REMARKS**

The courtesy of the interview granted Applicants' attorney on January 19, 2011 is appreciated. At the interview, the references used to support the grounds of rejection of the claims were discussed and particularly the Ding reference. For the reasons discussed in greater detail below, the Examiner agreed that Ding was not a valid prior art reference and that he would withdraw it as a reference against the claims of this case.

The present claims relate to a drug solution filling plastic ampoule and a method for making it having a flexible container body containing a drug solution molded from a tubular parison having three or more layers. The layers include an innermost and outermost layer composed of a polyolefin and an intermediate layer composed of blends of 20 to 50 wt % of a polyolefin and 50 to 80 wt % of a polycycloolefin.

In the Office Action of April 23, 2010 and as maintained in the Advisory Action of August 12, 2010, the Examiner rejected claims 1, 3, 11 and 12 under 35 U.S.C. § 103(a), for being obvious over Meierhoefer in view of Itoh further in view of Ding.

As discussed previously, Meierhoefer discloses a vial or ampoule in which a container body has only a single layer of plastic. Itoh discloses a multi-layer plastic container having at least three layers including inner and outer layers of a polyolefin and an intermediate layer of a cyclic olefin copolymer that can be formed by blow-molding. The Examiner, therefore, believes that it would be obvious to substitute the multi-layered structure of Itoh for the single layer of the ampoules of Meierhoefer. However, the combination of Meierhoefer and Itoh fails to disclose the claimed polyolefin-polycycloolefin blends and in the claimed ratios for the intermediate layer of

the container body. In a Declaration Under Rule 132 filed October 21, 2008, Applicants showed the excellent external quality that can be obtained for a container body when blends of polycycloolefin and polyolefin for the intermediate layer were used compared to when just a cyclic olefin copolymer was used.

Because of this, the Examiner cited Ding which discloses a container for medical fluids of a polymer composition of a cyclic olefin and a polyolefin (column 5, lines 16-34). Therefore, in the Examiner's opinion, it would have been obvious to "modify Meierhoefer and Itoh with the polyolefin-polycycloolefin blend as taught by Ding, since Meierhoefer calls for forming a container, filling it with fluid and sealing it." Paragraph 22 of the Office Action.

In the Advisory Action, last paragraph of paragraph 11, the Examiner argued that this was so because Itoh's layers are bonded together and Meierhoefer (sic Ding) calls for a polymer adapted for "solvent bonding." This then allows the COCs of Ding to be bonded or adhered by adding a solvent, joining the "partially dissolved" COC layer to other material and then allowing the solvent to evaporate. In the Examiner's opinion, this avoids water-based adhesives and keeps the overall water content low in the final article. Consequently, this is the motivation for modifying Meierhoefer and Itoh with Ding.

Itoh's multilayered flexible container is intended to hold a product for human consumption, such as toothpaste, foods, etc. Column 1, lines 15-18 and column 4, line 46. Moreover, the intermediate layer of a cyclic olefin copolymer is quite thin. As disclosed in column 16, line 65 to column 17, line 5 of Itoh, the total thickness of the container is from 100 to 1000  $\mu\text{m}$  and the thickness of the intermediate layer to the total

thickness is from 1.99 to 30:70. Thus the maximum thickness of the intermediate layer is only about 300 µm or .3 mm.

On the other hand, Ding teaches that "solvent bonding" requires exposing the surface to be bonded to the solvent to soften or dissolve the surface to form the required bond. Column 2, lines 33-40 of Ding.

As pointed out above, the Examiner argues that because of this solvent bonding technique it would have been obvious to substitute the blend of Ding for the cyclic olefin copolymer of the intermediate layer of Itoh. However, it is submitted that it would not have been obvious for at least the following reasons.

First of all, Itoh molds the containers by extruding the many layers through a die head to form a laminate and then blow-molding the laminate. Column 18, line 35 to column 19, line 5 of Itoh. In such a process, how would it be possible to simultaneously apply a solvent to an intermediate layer as required by Ding?

Secondly, in solvent bonding the layers are "dissolved" or at least softened. Since Itoh's intermediate layer is so thin, maximum .3 mm, such alteration of the layer could not be tolerated as it would clearly destroy or at least affect the integrity of the structure of the resulting container.

Thirdly, Itoh's containers are intended for holding substances such as toothpaste, food or the like. Solvents are by nature toxic, so they could not be tolerated in such an environment for this reason also.

Ding's solid objects may be able to tolerate solvent bonding on an exterior surface, but to suggest it could be used in Itoh's containers would require it to be used on interior layers of the containers.

Thus for at least these reasons, it is submitted that one skilled in the art would never have been motivated by the teachings of Ding to use blends of polyolefin and polycycloolefin for the intermediate layer of the container's of Itoh because the solvent bonding techniques taught for use with such blends could not be tolerated. They are, therefore, not an option in such a situation. As noted in M.P.E.P. § 2143.01V, the proposed modification cannot render the prior art being modified (Itoh) unsatisfactory for its intended purpose.

Needless to say, the problems caused by solvent bonding would be even greater if used in the present invention because the containers contain "a drug solution." Toxic substances and degradation of the structure of containers would clearly need to be avoided.

Accordingly, it is submitted that neither claim 1 nor claims 3, 11 and 12 dependent therefrom are obvious over the cited combination of references. Its withdrawal as a ground of rejection of these claims is therefore requested.

Regarding claims 13 and 15 and the rejection of the claims under § 103(a) for being obvious over Louviere in view of Itoh and Ding, Louviere is discussed in previous Replies and the comments about the reference set forth therein are incorporated herein by reference. Because the Examiner also relies on Ding to similarly modify Itoh in this rejection, for the same reasons expressed above with respect to claim 1, it is submitted that the reference cannot be relied on to teach or suggest the claimed intermediate layer as set forth in claim 13.

Accordingly, it is submitted that neither claim 13 nor claim 15 dependent therefrom are obvious over this combination of references.

The claims have only been amended to improve the structure of the claims and for clarity. Support for the capabilities of the intermediate layer can be found in the limitations deleted from the claims and page 12, lines 8-12 of the specification. Support for the amendments to claims 3 and 15 can be found on page 30, paragraph [0076] of the specification.

It is believed claims 1, 3, 11-13 and 15 are now in condition for allowance.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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